### Testimony of Brian J. Miller, M.D., M.B.A., M.P.H.

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## Nonresident Fellow American Enterprise Institute

#### Before the

U.S. Senate Committee on Health, Education, Labor and Pensions

On

"Making Health Care Affordable: Solutions to Lower Costs and Empower Patients."

July 31, 2025

Chairman Cassidy, Ranking Member Sanders, and distinguished members of the Committee:

My name is Brian Miller, and I practice hospital medicine at the Johns Hopkins Hospital. As an academic health policy analyst, I serve as an Associate Professor of Medicine and Business (Courtesy) at the Johns Hopkins University School of Medicine and as a Nonresident Fellow at the American Enterprise Institute. My research focuses on how we can build a more competitive and vibrant health sector to make healthcare more efficient, flexible, and personalized for patients. This perspective is based upon my prior regulatory experience at four federal regulatory agencies. Through my current role as a faculty member, I regularly engage with regulators, policymakers, and businesses in search of solutions to help create a better healthcare system for all. Today I am here in my personal capacity, and the views expressed are my own and do not necessarily reflect those of the Johns Hopkins University or the Johns Hopkins Health System, the American Enterprise Institute, the North Carolina State Health Plan, or the Medicare Payment Advisory Commission (MedPAC).

It is not easy to be a patient today nor an employer purchasing health benefits. Health care costs are rising for all, with total national health expenditures comprising 17.6%<sup>1</sup> of the gross domestic product. A key component of rising costs are rising prices for health services and drugs. The hospital sector, in particular, exhibits flat or negative labor productivity growth,<sup>2</sup> demonstrating the ills of monopoly, overregulation, and a consequential lack of innovation and growth. Historical policy choices have unintentionally placed a foot on the accelerator driving hospital consolidation, with hospital acquisition of outpatient practices due to the lack of site neutral payment<sup>3,4</sup> and the 340B program<sup>5,6</sup> both driving regulatory arbitrage as a strategy in place of improving clinical operations to better serve patients. Despite this, there is still much hope for using policy to help patients.

In my testimony today, I will focus on three practical areas where policy, technology, and real-world business operations can improve affordability for patients:

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<sup>&</sup>lt;sup>1</sup> Centers for Medicare & Medicaid Services. NHE Fact Sheet. www.cms.gov. Published September 6, 2023. <a href="https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet">https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet</a>

<sup>&</sup>lt;sup>2</sup> U.S. Bureau of Labor Statistics. *Private community hospitals labor productivity*. Published June 26, 2025. https://www.bls.gov/productivity/highlights/hospitals-labor-productivity.htm

<sup>&</sup>lt;sup>3</sup> Mansell L. Addressing Medicare spending and hospital consolidation with site-neutral payments.. Niskanen Center. Published March 4, 2024. https://www.niskanencenter.org/addressing-medicare-spending-and-hospital-consolidation-with-site-neutral-payments/

<sup>&</sup>lt;sup>4</sup> Albanese J. *Opportunities for Medicare site neutrality in 2025*. Paragon Health Institute. Published January 8, 2025. https://paragoninstitute.org/medicare/opportunities-for-medicare-site-neutrality-in-2025/

<sup>&</sup>lt;sup>5</sup> DiGiorgio AM, Winegarden W. Reforming 340B to Serve the Interests of Patients, Not Institutions. *JAMA Health Forum*. 2024;5(7):e241356-e241356. doi:10.1001/jamahealthforum.2024.1356

<sup>&</sup>lt;sup>6</sup> Wofford D, Kendall D. *One way to fix America's broken hospitals: Reform 340B.* Third Way. Published September 23, 2024. https://www.thirdway.org/report/one-way-to-fix-americas-broken-hospitals-reform-340b

- 1. Price transparency to empower patients and physicians
- 2. The role of pharmacy benefit managers and deploying transparency to empower employers
- 3. The North Carolina State Health Plan story

#### 1. Price transparency for consumers

Consumers regularly make a variety of tradeoffs on cost and quality in their daily lives when purchasing items small and large. Americans purchase a variety of everyday consumer products; in calendar year 2019, Americans consumed 612.4 million jars of peanut butter, while in 2023, Americans chose amongst at least 51 varieties across 9 brands. Consumers also make more complex, large purchases with greater transaction costs while weighing cost, quality, and other features. For example, in 2022, Americans purchased 13.6 million new and 39 million cars, with the new car market comprising 275 models<sup>10</sup> and untold thousands of potential combinations of colors and features. In addition to the purchase of goods, consumers also regularly decide – as part of their daily life – and choose between various providers of service weighing tradeoffs between price, convenience, and reputation. For example, each year over 273,000 independent shops<sup>11</sup> serve Americans in a variety of manners, including the \$8.1 billion oil change market.<sup>12</sup> Independent auto repair shops are notably recognized for trustworthiness, prices, and reputation, while chains were notable for convenience, <sup>13</sup> demonstrating some of the many choices that millions of Americans make every day weighing tradeoffs – in this case the integrated value of independent auto repair shops as compared to dealer service. To assume that American consumers cannot value and make tradeoffs incorrectly assumes that they lack agency.

Unfortunately, hospital markets - which market and sell a variety of products and services to consumers and employers – have historically lacked such transparency. In 2019, Executive Order 13877<sup>14</sup> directed multiple federal agencies, including the Department of Health and Human Services (HHS), to require the disclosure of negotiated rates and expected out-of-pocket costs for shoppable services, defined as "common services offered by multiple providers through the market, which patients can research and compare before making informed choices based upon price and quality." The order noted that 90% of the 300 highest-spending outpatient categories were considered shoppable. As part of the CY2020 hospital outpatient prospective payment system and ambulatory surgical center payment system annual rule, the Centers for Medicare and Medicaid Servies (CMS) required hospital disclosure of gross and payer-specific negotiated charges for a total of 300 services, including 70 mandatory shoppable services with the hospital selecting an additional 230 services. The 2020 implementation of CMS' price transparency for shoppable services 15 came with civil monetary penalties 16 of 300 \$/day per penalty, subsequently updated in 2021 by the Biden Administration for CY2022 to both increase with scale and cap, now registering up to \$5,500/day. 17

<sup>&</sup>lt;sup>7</sup> Statista Research Department. Topic: Peanut Butter Industry. Statista. Published March 18, 2024. https://www.statista.com/topics/2287/peanutbutter-industry/#topicOverview

<sup>&</sup>lt;sup>8</sup> Genovese P. Every major brand of peanut butter available in N.J., ranked, for National Peanut Butter Day 2023. NJ.com. Published January 24, 2023. https://www.nj.com/food/2023/01/every-major-brand-of-peanut-butter-available-in-nj-ranked-for-national-peanut-butter-day-2023.html <sup>9</sup> Bazen A. How Many Cars are Sold Each Year in the U.S.? ConsumerAffairs. Published January 17, 2024.

https://www.consumeraffairs.com/automotive/how-many-cars-are-sold-each-year-in-the-us.html

Tucker S. Americans Can Choose from About 275 Cars. They Choose These 30. *Kelley Blue Book*. Published October 17, 2022. https://www.kbb.com/car-news/americans-can-choose-from-about-275-cars-they-choose-these-30/

Auto Care Association. Survey: 84% of independent repair shops view vehicle data access as top issue for their business. PR Newswire. Published April 10, 2024. https://www.prnewswire.com/news-releases/survey-84-of-independent-repair-shops-view-vehicle-data-access-as-topissue-for-their-business-302113317.html

12 Grand View Research. U.S. Oil Change Service Market Size & Share Report, 2030. Published March 2025.

https://www.grandviewresearch.com/industry-analysis/us-oil-change-service-market-report

13 Preston B. Car owners favor independent repair shops. Consumer Reports. Published March 20, 2024. 

<sup>14</sup> Federal Register. Improving Price and Quality Transparency in American Healthcare To Put Patients First. Federal Register. Published June 27, 2019. https://www.federalregister.gov/documents/2019/06/27/2019-13945/improving-price-and-quality-transparency-in-american-healthcareto-put-patients-first

15 Federal Register. Medicare and Medicaid programs: CY 2020 Hospital Outpatient PPS policy changes and payment rates and Ambulatory

Surgical Center payment system policy changes and payment rates. Price transparency requirements for hospitals to make standard charges public. Federal Register. Published November 27, 2019. https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-andmedicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and

16 U.S. Department of Health and Human Services. Part 180—Requirements for Hospitals to Make Public a List of Their Standard Charges.

Published November 27, 2019. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180

<sup>&</sup>lt;sup>17</sup> Centers for Medicare & Medicard Services. CMS OPPS/ASC final rule increases price transparency, patient safety, and access to quality care. Published November 2, 2021. https://www.cms.gov/newsroom/press-releases/cms-oppsasc-final-rule-increases-price-transparency-patient-safetyand-access-quality-care

Regulators also deployed best practices in crafting price transparency regulations, noting that prices must be actionable, timely, and accessible.

Initial compliance was poor despite CMS' extension of the compliance deadline to January 1, 2021, with researchers demonstrating that 75 of the 100 highest revenue hospitals were noncompliant with at least 1 major requirement. Another study also showed that 55% of hospitals had not posted a machine-readable file. A broader 2022 study of 5,239 hospitals showed 729 or 13.9% had a machine-readable file but no shoppable display, 29.4% or 1,542 had a shoppable display and no machine-readable file, and 300 or 5.7% had both; unfortunately, 50.9% or 2,668 hospitals had neither. A November 2024 HHS OIG report demonstrated persistent, significant noncompliance with the hospital price transparency rule, with 37 of 100 hospitals service complying with 1 or both of the components of the rule, and analysts noting room for improvement in industry compliance and regulator enforcement.

Having clear information for shoppable services, including plain-language descriptions and both cash prices and payer-specific charges, available to the general public without a paywall is critical. With many hospitals in minor or material noncompliance and hospital price transparency a bipartisan priority, further work is still needed to ensure that hospitals meet both the explicit written language and spirit of price transparency regulations. Regular, routine auditing of large health systems through secret shopping — with a particular focus on tax-exempt institutions recognizing the significant financial benefits of tax exemption — is a must, along with meaningful implementation of financial penalties and publicization of noncompliance. CMS, state insurance commissioners, and other governmental and non-governmental stakeholders should also consider a public information campaign around shoppable services, with an aim to promote price awareness and engender price and non-price competition for health care services.

Transparency of hospital facility fees remains a critical arena for policy improvement. Regulators, including CMS and state bodies, should require *transparency of hospital outpatient department facility fees*, a critical consumer protection issue. While health policy experts can parse the technocratic payment regulatory policy difference between a facility billing on the physician fee schedule versus those billing as hospital outpatient departments, it is unrealistic to expect a consumer to know if a clinic is greater than 250 yards or less than 35 miles from the original hospital site and whether it was acquired and billing as an off-campus hospital outpatient department prior to November 2, 2015. Recognizing national news reports regarding the lack of hospital price transparency of facility fees, <sup>25,26</sup> policymakers should also encourage the *Federal Trade Commission to investigate hospital marketing practices around facility fees*, to ensure that consumers are appropriately informed.

<sup>&</sup>lt;sup>18</sup> Postma T, Grimsley H. *Hospital Price Transparency Final Rule Presenters*. Published December 3, 2019. https://www.cms.gov/files/document/2019-12-03-hospital-presentation.pdf

https://www.cms.gov/files/document/2019-12-03-hospital-presentation.pdf

19 Gondi S, Beckman AL, Ofoje AA, Hinkes P, McWilliams JM. Early Hospital Compliance With Federal Requirements for Price Transparency.

JAMA Intern Med. 2021;181(10):1396–1397. doi:10.1001/jamainternmed.2021.2531

<sup>&</sup>lt;sup>20</sup> Jiang JX, Polsky D, Littlejohn J, Wang Y, Zare H, Bai G. Factors Associated with Compliance to the Hospital Price Transparency Final Rule: a National Landscape Study. *J Gen Intern Med.* 2022 Nov;37(14):3577-3584. doi: 10.1007/s11606-021-07237-y. Epub 2021 Dec 13. PMID: 34902095; PMCID: PMC8667537.

<sup>&</sup>lt;sup>21</sup> Haque W, Ahmadzada M, Janumpally S, et al. Adherence to a Federal Hospital Price Transparency Rule and Associated Financial and Marketplace Factors. *JAMA*. 2022;327(21):2143–2145. doi:10.1001/jama.2022.5363

US Department of Health and Human Services. Not all selected hospitals complied with the Hospital Price Transparency Rule. Office of Inspector General. Office of Inspector General. Published November 8, 2024. <a href="https://oig.hhs.gov/reports/all/2024/not-all-selected-hospitals-complied-with-the-hospital-price-transparency-rule/">https://oig.hhs.gov/reports/all/2024/not-all-selected-hospitals-complied-with-the-hospital-price-transparency-rule/</a>
 Jiang J, Jiang M, Bai G. Enforcing Hospital Price Transparency: Lessons From CMS Actions. Health Affairs Forefront. Published online

December 3, 2024. doi:10.1377/forefront.20241202.645014

<sup>&</sup>lt;sup>24</sup> Federal Register. Medicare and Medicaid programs: CY 2020 Hospital Outpatient PPS policy changes and payment rates and Ambulatory Surgical Center payment system policy changes and payment rates. Price transparency requirements for hospitals to make standard charges public. Federal Register. Published November 27, 2019. <a href="https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and#p-1030">https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and#p-1030</a>
<sup>25</sup> Chuck E, Amorebieta M. After Cleveland Clinic expanded to Florida, patients say surprise fees followed. NBC News. Published July 24, 2025.

<sup>&</sup>lt;sup>25</sup> Chuck E, Amorebieta M. After Cleveland Clinic expanded to Florida, patients say surprise fees followed. NBC News. Published July 24, 2025 <a href="https://www.nbcnews.com/health/health-care/cleveland-clinic-florida-patients-facility-fees-rcna219599">https://www.nbcnews.com/health/health-care/cleveland-clinic-florida-patients-facility-fees-rcna219599</a>

<sup>&</sup>lt;sup>26</sup> Chuck E, Amorebieta M. Did your doctor's office charge you a "facility fee"? Here's what to know. *NBC News*. Published July 24, 2025. https://www.nbcnews.com/health/health-care/facility-fees-what-patients-know-doctors-appointment-hospital-visit-rcna220193

Other arenas of price transparency have attracted regulatory attention, including a 2020 regulation targeting price transparency regulations affect group health plans,<sup>27</sup> as well as the proposal and subsequent implementation of a real time prescription benefits tool for Part D,<sup>28,29</sup> a development with the potential to change prescribing practices across payer markets. Researchers studied the implementation<sup>30</sup> of a real-time prescription benefit tool (RTPB) and found no change in prescription expenditures. However, the study failed to assess for a more realistic range of expected outcomes. Implementation of a RTPB would be more likely to change prescribing habits to *avoid* increased costs, as opposed to decreasing costs. Further research is needed to determine if RTPB tools have helped beneficiaries avoid drug price increases due to changes in benefit design, switching between preferred and non-preferred products, along with the incidence and avoidance of repeat physician visits for the purpose of prescribing or alternatively filling a new retail prescription within 2 weeks of the initial prescribing for the same condition.

As a next step beyond requiring hospital price transparency, policymakers should support price transparency at the point of care to empower patients and physicians together in shared decision-making. Evidence demonstrates that just providing prices to employees via an online tool is not frequently not helpful. A study of two large employers providing a price transparency tool found no change in healthcare spending and employee uptake,<sup>31</sup> likely as it was not tied to the point of sale as public-facing hospital or electronic health record price transparency. Fitting with the Trump Administration's initiation of and Biden Administration's continued support of price transparency for shoppable outpatient services, research suggests that price transparency is also less impactful in the inpatient setting. Work has demonstrated minimal to no impact of price transparency on ordering labs with display of Medicare prices in the inpatient setting,<sup>32</sup> commonly used imaging studies<sup>33</sup> and inpatient pharmaceuticals,<sup>34</sup> with one study showing a modest impact (~8% decrease) on inpatient lab utilization.<sup>35</sup>

In contrast, research dating back to 1990 shows that the display of prices reduced outpatient diagnostic test ordering by 14% and that after the intervention ended, only half that effect was sustained.<sup>36</sup> This fits with real-world evidence from other markets that pricing information matters at the *point of purchase* or action. Critics have long suggested that price transparency is a burden on small businesses, such as independent private practices, while evidence suggests the contrary: that larger enterprises are less likely to provide transparent prices.<sup>37</sup> Price transparency at the point of service is a policy supported by physician leaders in organized medicine, such as former American Medical Association (AMA) President Jesse Ehrenfeld, M.D., M.P.H., <sup>38</sup> members of the antitrust bar with experience at national competition agencies, <sup>39</sup> and the AMA code of ethics, which envisions the physician as proponents of cost-effective medical practice and a stewards of the health care dollar: <sup>40</sup>

<sup>&</sup>lt;sup>27</sup> Federal Register. *Transparency in Coverage. Federal Register*. Published November 12, 2020. https://www.federalregister.gov/documents/2020/11/12/2020-24501/transparency-in-coverage

https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage

28 Centers for Medicare & Medicaid Services. Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) fact sheet.

Published May 12, 2025. https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet

fact-sheet

29 Centers for Medicare & Medicaid Services. *E-Prescribing*. Published February 22, 2024. https://www.cms.gov/medicare/regulations-guidance/electronic-prescribing

guidance/electronic-prescribing

30 Zink A, Wehrly D, Bozzi D, et al. Prescription Use and Spending After the Introduction of a Real-Time Prescription Benefit Tool. JAMA Netw Open. 2025;8(7):e2519038. doi:10.1001/jamanetworkopen.2025.19038

<sup>&</sup>lt;sup>31</sup> Desai S, Hatfield LA, Hicks AL, Chernew ME, Mehrotra A. Association Between Availability of a Price Transparency Tool and Outpatient Spending. *JAMA*. 2016;315(17):1874–1881. doi:10.1001/jama.2016.4288

<sup>&</sup>lt;sup>32</sup> Sedrak MS, Myers JS, Small DS, et al. Effect of a Price Transparency Intervention in the Electronic Health Record on Clinician Ordering of Inpatient Laboratory Tests: The PRICE Randomized Clinical Trial. *JAMA Intern Med.* 2017;177(7):939–945. doi:10.1001/jamainternmed.2017.1144

<sup>&</sup>lt;sup>33</sup> Durand DJ, Feldman LS, Lewin JS, Brotman DJ. Provider cost transparency alone has no impact on inpatient imaging utilization. *J Am Coll Radiol*. 2013 Feb;10(2):108-13. doi: 10.1016/j.jacr.2012.06.020. Epub 2012 Dec 28. PMID: 23273974.

 <sup>&</sup>lt;sup>34</sup> Conway S, Brotman D, Pinto B, Merola D, Feldman L, Miller R, Shermock K. Impact of Displaying Inpatient Pharmaceutical Costs at the Time of Order Entry: Lessons From a Tertiary Care Center. *J Hosp Med.* 2017 Aug;12(8):639-645. doi: 10.12788/jhm.2779. PMID: 28786430.
 <sup>35</sup> Feldman LS, Shihab HM, Thiemann D, et al. Impact of Providing Fee Data on Laboratory Test Ordering: A Controlled Clinical Trial. *JAMA Intern Med.* 2013;173(10):903–908. doi:10.1001/jamainternmed.2013.232

<sup>&</sup>lt;sup>36</sup> Tierney WM, Miller ME, McDonald CJ. The effect on test ordering of informing physicians of the charges for outpatient diagnostic tests. *N Engl J Med.* 1990 May 24;322(21):1499-504. doi: 10.1056/NEJM199005243222105

<sup>&</sup>lt;sup>37</sup> Batra A, Candon M. Price Transparency for Primary Care Office Visits and Routine Tests: Results From a 2016 Audit Study. *Inquiry*. 2022 Jan-Dec;59:469580221092122. doi: 10.1177/00469580221092122. PMID: 35412869; PMCID: PMC9008822.

<sup>&</sup>lt;sup>38</sup> Miller BJ, Slota JM, Ehrenfeld JM. Redefining the Physician's Role in Cost-Conscious Care: The Potential Role of the Electronic Health Record. *JAMA*. 2019;322(8):721–722. doi:10.1001/jama.2019.9114

<sup>&</sup>lt;sup>39</sup> Miller, B.J., Mandelberg, M.C., Griffith, N.C. et al. Price Transparency: Empowering Patient Choice and Promoting Provider Competition. *J Med Syst* **44**, 80 (2020). https://doi.org/10.1007/s10916-020-01553-2

<sup>&</sup>lt;sup>40</sup> AMA Council on Ethical and Judicial Affairs. AMA Code of Medical Ethics' opinion on physician stewardship. *AMA J Ethics*. 2015;17(1):1044-1045. https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-07/coet1-1511.pd

...Encouraging health care administrators and organizations to make cost data transparent (including cost accounting methodologies) so that physicians can exercise well-informed stewardship; ensuring that physicians have the training they need to be informed about health care costs and how their decisions affect overall health care spending...

Unfortunately, despite the ethos of shared decision-making, clinical operations and federal regulations remain over a decade behind. The exam room remains a critical venue for patients and physicians to make decisions together regarding the use of many commodity services, such as imaging and diagnostic labs, or the titration, initiation, or discontinuation of one of many thousands of choices of prescription drugs. Yet for many routine products and services, both patients and physicians remain unaware of prices – akin to walking through a Walmart grocery aisle with no prices. A now-dated 2004 study found that 64% of ambulatory physicians were unaware of whether the prescribed drug was on the formulary.<sup>41</sup>

Instead of burdening patients at the pharmacy check-out counter or off-campus radiology department subsequent to a physician's visit, necessitating return service to adjust a plan of care, regulators, health systems, and health plans could work to drive pricing for many items and services to the point of care – embedded in the electronic health record. By driving pricing to the point of care for pharmaceuticals, imaging, diagnostic labs, and other services, we can better operationally integrate care delivery and financing to provide patients with a more seamless experience. For example, communication of formulary status (on/off formulary), tiering, and patient financial responsibility in EHRs in the exam room could drive cost-effective clinical practice and increase patient convenience. Critics might argue that this intervention would be unlikely to have an effect, both disregarding prior established evidence and underestimating how consumer learning and clinician use vary as routine practices shift due to changes in market penetration of price transparency. While further education of physicians, residents, nurses, and other practitioners would be required along human factors engineering of clinical interfaces to drive adoption in a community setting, the National Coordinator for Health Information Technology should operationalize price transparency in the EHR through meaningful use or other regulations. By seamlessly integrating pricing, benefit information and other components into workflows, we can expand access and convenience rather than burdening patients and physicians.

#### 2. The role of pharmacy benefit managers and deploying transparency to empower employers

After the passage of the 1962 Kefauver-Harris Amendment, the FDA contracted with the National Academy of Sciences to study over 3,400 drugs approved only for safety between 1938 and 1962, with the Drug Efficacy Study Implementation (DESI) study published as a series of Federal Register notices. Since 1950, the FDA has approved an estimated 1,200 new drugs, with pharmaceutical product developers transforming HIV from a death sentence into a chronic disease, while the eventual advent of weekly basal insulin (currently a subject of product development) would represent a revolutionary innovation for diabetes treatment and adherence. Continued pharmaceutical product innovation, especially in outpatient prescription drugs, benefits patients, but simultaneously creates continuous choice overload for patients and employers. Rather than destroying innovation, entities emerged to serve as a choice filter.

Pharmacy benefit managers, or PBMs, address the challenge of continuous choice overload in the prescription drug market. As a dynamic market-based intervention, PBMs can help plan sponsors and filter choices, serving as an important alternative to government-run centralized authorities present in other countries. Pharmaceutical product developers are constantly creating new products – a significant net benefit to society of which many of us will individually benefit from – and have an interest in selling them regardless of their *relative* performance. FDA approval is predicated on an absolute standard of "safe and effective" and does not necessarily require head to head

<sup>&</sup>lt;sup>41</sup> Shih YC, Sleath BL. Health care provider knowledge of drug formulary status in ambulatory care settings. *Am J Health Syst Pharm*. 2004 Dec 15;61(24):2657-63. doi: 10.1093/ajhp/61.24.2657. PMID: 15646700.

<sup>&</sup>lt;sup>42</sup> U.S. Food & Drug Administration. *Drug Efficacy Study Implementation (DESI)*. FDA. Published online August 28, 2020. https://www.fda.gov/drugs/enforcement-activities-fda/drug-efficacy-study-implementation-desi

<sup>&</sup>lt;sup>43</sup> Munos B. Lessons from 60 years of pharmaceutical innovation. *Nature Reviews Drug Discovery*. 2009;8(12):959-968. doi:https://doi.org/10.1038/nrd2961

 <sup>44</sup> Mahungu TW, Rodger AJ, Johnson MA. HIV as a chronic disease. *Clin Med (Lond)*. 2009;9(2):125-128. doi:10.7861/clinmedicine.9-2-125
 45 Deeks SG, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. *Lancet*. 2013;382(9903):1525-1533. doi:10.1016/S0140-6736(13)61809-7

<sup>&</sup>lt;sup>46</sup> Rosenstock J, Bain SC, Gowda A, et al. Weekly Icodec versus Daily Glargine U100 in Type 2 Diabetes without Previous Insulin. N Engl J Med. 2023;389(4):297-308. doi:10.1056/NEJMoa2303208

product comparisons. Instead, FDA review facilitates subsequent more detailed, real-world evaluations of efficacy, leaving to post-market actors such as PBMs the need to assess improved performance in sub-populations, the decreased need for burdensome testing or monitoring, or other clinical features of drugs that have real world clinical and economic implications.

In a world where there are thousands of prescriptions drugs for a litany of conditions and our health care system in Cy2021 spent \$421 billion on drugs before rebates,<sup>47</sup> PBMs serve as a technocratic filter and organizer of the outpatient prescription drug benefit in a complex financing and distribution environment (see diagram below), assisting employers and plan sponsors in managing the outpatient prescription drug benefit.

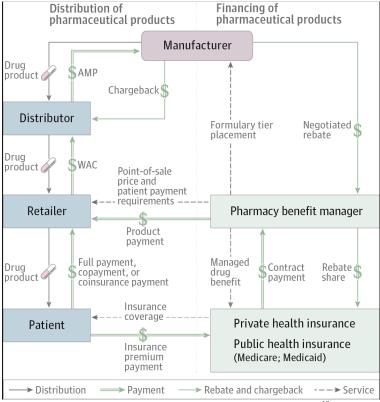


Figure 1: Diagram of the Pharmacy Supply Chain<sup>48</sup>

PBMs serve several core functions in financing and distribution <sup>49</sup> for the outpatient prescription drug benefit, including formulary design, tiering, distribution network construction (broad or narrow; retail chain and mail-order), specialty pharmacy management, and information management. Other adjacent pharmacy administrative service enterprises have served to make product acquisition seamless for consumers, such as real-time benefits adjudication at the pharmacy check-out counter, arguably the only place in care delivery where real-time benefits adjudication happens consistently. Yet, PBM functions still shape clinical decision-making with formulary construction a critical task. Scientific and clinical evidence is frequently open to a range of reasonable interpretations, and the assessment of clinical evidence behind safety and efficacy in the real world is varied. Acknowledging this reality, a single central authority serving the role of a PBM (i.e. the federal government) is unlikely to best serve the needs of an

<sup>&</sup>lt;sup>47</sup> Parasrampuria S, Murphy S. *Trends in Prescription Drug Spending*, 2016-2021. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Published September 2022. https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf

<sup>&</sup>lt;sup>48</sup> Dabora MC, Turaga N, Schulman KA. Financing and Distribution of Pharmaceuticals in the United States. *JAMA*. 2017;318(1):21–22. doi:10.1001/jama.2017.5607

<sup>&</sup>lt;sup>49</sup> Dabora MC, Turaga N, Schulman KA. Financing and Distribution of Pharmaceuticals in the United States. *JAMA*. 2017;318(1):21–22. doi:10.1001/jama.2017.5607

increasingly diverse clinical population.<sup>50,51</sup> Thus, if policymakers are to meaningfully support pharmaceutical product development and not prematurely foreclose national markets to product innovation as other countries do, patients and employers need a diversity of entities with expertise and specialization to help to filter and relatively value prescription drug choices. Fundamentally, PBMs provide technocratic guidance and advocacy in a complex and ever-changing arena – drug development – and as a result their expertise and specialization drive employers to get better outcomes than they would have achieved on their own.

At the same time, there are policy opportunities to improve PBMs for the stakeholders whom they serve. When PBMs depended upon fees, it was relatively clear that they served those who paid their fees: health plans and plan sponsors (i.e. employers). The rebate model has upended this, blurring the agency of the PBM to drive rebate dollars and manufacturer payments, as opposed to payer fees. At times, it is less clear who the primary customer is while simultaneously shifting PBM formulary strategy – the filter of pharmaceutical innovation has become cloudy.

There is thus room for additional transparency to the stakeholders whom PBMs serve, with the anger directed at PBMs due to the lack of understanding and transparency of a complex pharmaceutical marketplace. Many stakeholders have proposed rigid interventions that are not flexible over time, with direct regulation of contracting or policy proposals and interventions built around direct federal price regulation of drugs through other means (e.g. the Inflation Reduction Act). Centralized administration price regulation as a static, rigid intervention tends to be harmful in multiple ways:

- 1. Significant off target effects such as innovation impacts
- 2. Unintentionally generating a requirement for continued legislative intervention as the real world shifts. This reflects a recurring theme across 30 years of drug pricing law and regulations<sup>52</sup> akin to constantly weeding a garden (a highly unrealistic political economy)
- 3. Static interventions are unable to adapt to a changing and dynamic world

The Fee-for-Service Medicare program is the best example of the failures of centralized price and contracting regulation. For example, there is a statutory three-day acute hospital stay requirement for beneficiary access to post-acute care, a requirement established in statute in 1967, when the average length of stay was 13.8 days and there was no observation status.<sup>53</sup> Patients and physicians today are still wrestling with this barrier, causing problems for up to 24,000 Medicare beneficiaries annually who need and cannot access post-acute care.<sup>54</sup>

Instead, policymakers should focus on dynamic interventions that can change over time as part of a natural system, recognizing that markets are intrinsically chaotic and that continued regulatory and legislative interventions lasering specific practices are unlikely to be effective in the long term. Transparency for plan sponsors/employers while preserving the choice of contracting models for PBMs – whether it is rebates, fee based or some other model – would preserve the dynamic nature of core PBM functions as a filterer and constructor of the outpatient prescription drug benefit, while empowering employers and plan sponsors with information to more fully understand the tradeoffs that they are making (i.e. preferencing spread pricing with rebates or alternatively fee-based arrangements). Policymakers must also recognize that PBM tools themselves are not necessarily problematic; for example, rebates can and do help employers fund other health benefits for their employees. Rather, the issue lies in the lack of transparency and insight into the risks and benefits of said tools for employers and plan sponsors, and how incentives and formularies have changed as a consequence.

Transparency requirements could encompass a range of policy options, from how rebates influence formulary choices to fee structures to rebate agreements – all areas worthy of further study. Another area worthy of further study are dynamic facilitators of transparency, such requiring fiduciary responsibility for PBMs, a potentially

<sup>&</sup>lt;sup>50</sup> Sorace J, Millman M, Bounds M, et al. Temporal variation in patterns of comorbidities in the medicare population. *Population health management*. 2013;16(2):120-124. doi:https://doi.org/10.1089/pop.2012.0045

<sup>&</sup>lt;sup>51</sup> Sorace J, Wong H, Worrall C, Kelman J, Saneinejad S, MaCurdy T. The Complexity of Disease Combinations in the Medicare Population. *Population Health Management*. 2011;14(4):161-166. doi:https://doi.org/10.1089/pop.2010.0044

<sup>&</sup>lt;sup>52</sup>Williams D, Zima SC, Miller BJ. Reforming Drug Price Regulation: Using Tools That Work. *PubMed*. 2025;62:469580251335844-469580251335844. doi:https://doi.org/10.1177/00469580251335844

<sup>&</sup>lt;sup>53</sup> Patel N, Slota JM, Miller BJ. The Continued Conundrum of Discharge to a Skilled Nursing Facility After a Medicare Observation Stay. *JAMA Health Forum*. 2020;1(5):e200577. doi:10.1001/jamahealthforum.2020.0577

<sup>&</sup>lt;sup>54</sup> Sheehy A. Testimony before the United States Senate Special Committee on Aging Admitted or Not? The Impact of Medicare Observation Status on Seniors. Published 2014. <a href="https://www.hospitalmedicine.org/globalassets/policy-and-advocacy/letters-to-policymakers-pdf/hospitalist-testifies-before-united-states-senate-special-committee-on-aging-july-30.pdf">https://www.hospitalmedicine.org/globalassets/policy-and-advocacy/letters-to-policymakers-pdf/hospitalist-testifies-before-united-states-senate-special-committee-on-aging-july-30.pdf</a>

disruptive shift. Recognizing PBM market consolidation,<sup>55</sup> that PBM-network disputes can be disruptive<sup>56,57</sup> albeit they promote PBM growth and innovation,<sup>58</sup> and that the FTC has approved decades of PBM mergers,<sup>59</sup> policymakers should also drive competition and require the Federal Trade Commission to undertake a retrospective review of PBM mergers, in order to improve PBM merger review (akin to prior agency work on hospital mergers)<sup>60</sup> and ensure a more competitive future marketplace. In general, policy should focus on dynamic interventions to create a more competitive and robust market for pharmacy benefits, as opposed to directly regulating the choices and incentives of employers and PBMs. Employers and plan sponsors need clarity of choices and tradeoffs with clear incentives, while PBMs need to retain the freedom to contract as they see fit to best meet the needs of their customers. Finally, PBMs screen choices and shape environments in a market-based fashion when the alternative is centralization, a choice that has fundamentally failed in other health care markets.

#### 3. The North Carolina State Health Plan Story

In addition to price transparency targeted at consumers, employers have agency and can deploy the tools of managed care to improve affordability of care for and manage the health of employed populations. By explicitly designing and making transparent cost and quality tradeoffs for both patients and their physicians, self-insured employers can drive affordability and improve quality even in highly consolidated markets.

North Carolina (NC) is a market with rising consolidation and prices, as large systems grew into the NC market – with HCA acquiring Mission Health, <sup>61,62</sup> Risant purchasing Cone Health, <sup>63</sup> and Atrium acquiring WakeForest Baptist<sup>64</sup> before subsequently merging with Advocate Aurora. <sup>65</sup> Local systems also have become regionally dominant through mergers and expansion into new regions. For example, UNC's attempt to exempt itself from federal antitrust oversight through state action <sup>66</sup> after decades of mergers two decades of acquisitions including Rex, <sup>67</sup> High Point Regional, <sup>68</sup> Southeastern Health, <sup>69</sup> Johnston Health, <sup>70</sup> Blueridge, <sup>71</sup> and many others. Similarly,

<sup>&</sup>lt;sup>55</sup> Qato DM, Chen Y, Van Nuys K. Pharmacy Benefit Manager Market Concentration for Prescriptions Filled at US Retail Pharmacies. JAMA. 2024;332(15):1298–1299. doi:10.1001/jama.2024.17332

<sup>&</sup>lt;sup>56</sup> Seaman, M. "Walgreen 1Q profit drops on Express Scripts fight." Seattle Times December 21, 2011.

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<sup>&</sup>lt;sup>57</sup> Seaman, M. "Walgreens, Express Scripts sign new agreement." Seattle Times July 19, 2012. <a href="https://www.seattletimes.com/business/walgreenexpress-scripts-sign-new-agreement/">https://www.seattletimes.com/business/walgreenexpress-scripts-sign-new-agreement/</a>
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<sup>&</sup>lt;sup>58</sup> Walgreens and Prime Therapeutics Agree to Form Strategic Alliance. August 29, 2016. <a href="https://www.walgreensbootsalliance.com/news-media/press-releases/2016/walgreens-and-prime-therapeutics-agree-to-form-strategic-alliance-includes-retail-pharmacy-network-agreement-and-combines-companies-central-specialty-pharmacy-and-mail-service-businesses">https://www.walgreensbootsalliance.com/news-media/press-releases/2016/walgreens-and-prime-therapeutics-agree-to-form-strategic-alliance-includes-retail-pharmacy-network-agreement-and-combines-companies-central-specialty-pharmacy-and-mail-service-businesses</a>

<sup>&</sup>lt;sup>59</sup> https://www.ftc.gov/sites/default/files/documents/closing\_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf

<sup>&</sup>lt;sup>60</sup> Vita MG, Sacher S. The Competitive Effects of Not-for-Profit Hospital Mergers: A Case Study. *Journal of Industrial Economics*. 2001;49(1):63-84. doi:https://doi.org/10.1111/1467-6451.00138

<sup>61</sup> Health Law & Policy Program - Wake Forest Law. Wake Forest Law. Published April 15, 2025. https://hlp.law.wfu.edu/wp-content/uploads/sites/11/2024/06/HCA-Mission-Lead-Up-To-HCA-Sale-working-draft-WFU.ndf

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<sup>&</sup>lt;sup>63</sup> Cone Health. Risant Health Closes Cone Health Transaction, Adds Second Health System in Nine Months. Published December 3, 2024. <a href="https://www.conehealth.com/news/news-search/2024-news-releases/risant-health-closes-cone-health-transaction-adds-second-health-/">https://www.conehealth.com/news/news-search/2024-news-releases/risant-health-closes-cone-health-transaction-adds-second-health-/</a>
<sup>64</sup> Atrium Health News. Atrium Health and Wake Forest Baptist Health Combine, Create Next-Generation Academic Health System. Atrium

<sup>&</sup>lt;sup>64</sup> Atrium Health News. Atrium Health and Wake Forest Baptist Health Combine, Create Next-Generation Academic Health System. Atrium Health. Published October 9, 2020. <a href="https://atriumhealth.org/about-us/newsroom/news/2020/10/atrium-health-and-wake-forest-baptist-health-combine-create-next-generation-academic-health-system">https://atriumhealth.org/about-us/newsroom/news/2020/10/atrium-health-and-wake-forest-baptist-health-combine-create-next-generation-academic-health-system</a>

<sup>&</sup>lt;sup>65</sup> Atrium Health News. *Advocate Aurora Health and Atrium Health Complete Combination. Atrium Health.* Published December 2, 2022. https://atriumhealth.org/about-us/newsroom/news/2022/12/advocate-aurora-health-and-atrium-health-complete-combination

<sup>&</sup>lt;sup>66</sup> Hoban R. Proposed bill could give UNC Health a green light to expand without as much oversight. *North Carolina Health News*. Published May 2, 2023. https://www.northcarolinahealthnews.org/2023/05/02/proposed-bill-unc-health-restructure-antitrust/

<sup>&</sup>lt;sup>67</sup> Besthoff L, Whisnant C, Wallace K. Rex Healthcare Agrees To Merge With UNC Health Care. WRAL.com. Published August 3, 2006. https://www.wral.com/story/140628/

<sup>68</sup> Johnson PB, High Point Enterprise. High Point Regional to merge with UNC Health Care. WXII. Published September 27, 2012. https://www.wxii12.com/article/high-point-regional-to-merge-with-unc-health-care/2047518

<sup>&</sup>lt;sup>69</sup> Stradling R. Another small rural North Carolina hospital joins the UNC Health system. *Raleigh News & Observer*. Published December 5, 2020. <a href="https://www.newsobserver.com/news/local/article247605095.html">https://www.newsobserver.com/news/local/article247605095.html</a>

<sup>&</sup>lt;sup>70</sup> UNC Health REX. UNC REX and Johnston Health approve plan to expand partnership. Published September 27, 2019.

https://www.rexhealth.com/rh/about/news-media/2019/unc-rex-and-johnston-health-approve-plan-to-expand-partnership/

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Duke purchased Lake Norman Regional Medical Center, 72 and Novant Health has attempted to buy Community Health Systems hospitals, 73,74 subsequent to other growth. Health system monopolies and rising medical spending trends drove a projected >\$500M deficit for CY2026<sup>75</sup> and a total deficit of \$949M by the end of CY2027. <sup>76</sup> Options for closing the financial deficit became even more limited after Hurricane Helene damaging the state to the tune of an economic cost of \$59.6 billion in September of 2024,<sup>77</sup> further straining state government finances. The majority of plan spending derives from outpatient facility services and professional services (see figure below), many of which are purchased from large integrated health systems.

TOP IMPACTABLE CATEGORIES	Percent of SPEND	Percent of MEDICAL SPEND
INPATIENT	10.6%	15.4%
Surgical	5.1%	7.3%
Maternity and Neonate	1.7%	2.5%
OUTPATIENT FACILITY	26.1%	37.9%
Surgery	9.4%	13.7%
Radiology	3.1%	4.5%
Lab/Pathology	1.0%	1.5%
PROFESSIONAL SERVICES	30.3%	44.1%
E&M and Preventive	11.8%	17.1%
Procedural	3.8%	5.5%
Mental Health	3.4%	4.9%
Office Administered Drugs	2.5%	3.7%
Therapies	2.4%	3.5%
Radiology	2.0%	2.9%
Lab/Pathology	1.6%	2.3%

Figure 2: Sources of spend for NC SHP<sup>78</sup>

In the setting of financial challenges and rising costs for services that could be procured in a more competitive fashion, the State Health Plan (SHP) worked to update benefit design and transition away from an any-willingprovider network to a preferred provider model in order to steer employees to higher quality, more cost-efficient providers. 79 First, the SHP will aim to prioritize low-cost, high-quality independent primary care providers to counteract consolidation and support small businesses across the state. Benefit design will drive volume to these practices, as SHP members will face a lower - \$10-15 - copay coupled with elimination of medical prior authorization for preferred primary care providers to improve access. In addition to a reduction in administrative burden, primary care providers will receive per-member-per-month care management fees and financial steerage bonuses for referring patients to low cost imaging and lab providers, recognizing that many consolidated systems frequently raise prices for these important, routine commodity services. Preferred primary care providers will also

<sup>&</sup>lt;sup>72</sup> Lopez S. Duke Health Completes Acquisition of Lake Norman Regional Medical Center. *Duke Health*. Published April 1, 2025. https://corporate.dukehealth.org/news/duke-health-completes-acquisition-lake-norman-regional-medical-center

<sup>&</sup>lt;sup>73</sup> Federal Trade Commission. FTC Sues to Block Novant Health's Acquisition of Two Hospitals from Community Health Systems. Published January 25, 2024. https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-sues-block-novant-healths-acquisition-two-hospitals-community-health-systems
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<sup>&</sup>lt;sup>76</sup> Brechbiel R. Performance Audit Confirms Deficit Projections of State Health Plan. Nc. gov. Published June 26, 2025.

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<sup>78</sup> See slide 15, "State Health Plan Board of Trustees Meeting." North Carolina State Health Plan. May 20, 2025. Available from: https://www.shpnc.gov/documents/board-trustees/board-trustees-presentation-5202025/download?attachment

See slides 16 - 24, "State Health Plan Board of Trustees Meeting." North Carolina State Health Plan. May 20, 2025. Available from: https://www.shpnc.gov/documents/board-trustees/board-trustees-presentation-5202025/download?attachment

receive additional incentives for referrals to specialty practices participating in bundles to drive quality/access/cost efficiency. These transparency initiatives will be timely, accessible and meaningful, using explicit networks and benefit design to help steer employees to more efficient primary care, with subsequent transparency and incentives to promote shared decision-making between patients and their primary care physicians at the point of care.

To reduce the cost of specialty care, the SHP will compete specialty care bundles between independent providers and large systems for preferred status, targeting high-cost, critical services that have strong evidence of cost-quality relationships, such as knees, hips, shoulders, <sup>80,81,82,83</sup> and inpatient cardiology. <sup>84,85,86</sup> Providers will gain certainty of volume, stable pricing, and the elimination of medical prior authorization. Behavioral health providers will be paid at 140% of Medicare's Fee-for-Service rates. For employees, transparent tradeoffs between preferred and non-preferred specialty providers will be made clear as part of the network design and updated benefit package, necessitating partnership between employee associations and the SHP to drive volume to preferred specialty providers.

Finally, Medicare retirees will be protected under the employer group waiver plan (EGWP, a group Medicare Advantage plan) with enriched benefits and an open network, coupled with some utilization review. The EGWP retiree product will undergo few to nominal changes as its fixed, capitated budget will provide both better structural budgeting for the plan, while simultaneously offering better cost sharing for members. In contrast, the Medigap plan with increasing costs, little to no utilization review, and no network design will experience relatively increasing premiums, incenting retirees to transition to the more cost-effective product that offers richer benefits in exchange for implementation of some utilization review.

In summary, employers have agency and can use the tools of managed care to gently direct their members to networks of preferred providers, making financial tradeoffs clear to employees both through the use of benefit design and through transparency for patients and physicians at the point of care. These, and other changes focused on transparency, will serve to close a large financial gap without additional state funding, preserving benefits, and improving affordable access for patients.

#### 4. Conclusion

Policymakers have many options to drive affordability through transparency for patients, physicians, and employers. Policymakers and regulators can build upon previous hospital price transparency efforts by driving auditing, enforcement, consumer-directed communications, and hospital penalties as appropriate, while also pursuing transparency of facility fees. Technology and innovation can be used to drive price transparency to the point of care, empowering patients and physicians to undertake shared decision-making in care, while PBM transparency can provide clarity of agency and preserve contracting flexibility for PBMs and employers and other plan sponsors. Finally, employers have opportunities to implement basic managed care practices and health financing tools to drive affordability.

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<sup>&</sup>lt;sup>84</sup> Freeman JV, Wang Y, Curtis JP, Heidenreich PA, Hlatky MA. Physician Procedure Volume and Complications of Cardioverter-Defibrillator Implantation. *Circulation*. 2012;125(1):57-64. doi:https://doi.org/10.1161/circulationaha.111.046995

<sup>&</sup>lt;sup>85</sup> Ślicker K, Lane WG, Oyetayo OO, et al. Daily cardiac catheterization procedural volume and complications at an academic medical center. *Cardiovascular Diagnosis and Therapy*. 2016;6(5):446-452. doi:https://doi.org/10.21037/cdt.2016.05.02

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